

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### **I. Status of the Claims**

Claims 1-26 and 29-30 were cancelled previously. Claims 27 and 28 have been amended to delete the term “prevention.” Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 27-28 and 31-45 will be pending.

### **II. Rejection of Claims under 35 U.S.C. § 112, first paragraph**

The Examiner rejected claims 27-28 and 31-45 for alleged lack of enablement. Applicants respectfully traverse the rejection.

The Examiner contends that the specification fails to enable prevention of a bone mineral density reduction. Without acquiescing to the stated basis for the rejection, Applicants choose to advance the prosecution by deleting “prevention” from the claims at issue. Accordingly, Applicants respectfully request withdrawal of the rejection.

### **III. Rejection of Claims under 35 U.S.C. § 102(b)**

The Examiner rejected claims 27-28, 34-37, and 41-45 for alleged anticipation by PCT Publication No. WO 02/085393 by Bourges-Sevenier et al. For the convenience of discussion, the corresponding U.S. Patent Application Publication No. 2005/0019438, published in English, is referred to as “Bourges-Sevenier” below. Applicants respectfully traverse the rejection.

Bourges-Sevenier describes an extract, from certain species of female hop cones, that contains “xanthohumol, isoxanthohumol and 8-prenylnaringenine, *in defined weight proportions*,” and that is useful for treating physiological disorders related to perimenopause or menopause. Abstract (emphasis added). More specifically, the three constituents are said to present in the

amount of from 1 to 30 g, from 0.01 to 50 g of isoxanthohumol and from  $0.5 \times 10^{-3}$  to 10 g, respectively. For example, see paragraphs [0008] and [0011] of Bourges-Sevenier.

By definition, therefore, the reference teaches an extract that must embody the *combined* activity of three ingredients: xanthohumol, isoxanthohumol, and 8-prenylnaringenine. By contrast, isoxanthohumol is the *only* essential compound, *i.e.*, no further active compound is necessary, for inhibiting bone mineral density reduction or for treating or amelioring osteoporosis in Applicants' invention, as claims 27 and 28 prescribe.

In keeping with this distinction, the specification compares the activity of isoxanthohumol with that of xanthohumol and 8-prenylnaringenine (Test 4, pages 33-35). As demonstrated at page 34, lines 25-33, as well as in Figure 5 and Figure 6, while the bone mineral density reduction was significantly ameliorated by isoxanthohumol, the amelioration was not observed with either iso- $\alpha$  acids (containing xanthohumol and isohumulons) or 8-prenylnaringenine. The specification further demonstrates that, unlike 8-prenylnaringenine, isoxanthohumol has little or no adverse side effects, such as undesired uterine weight increase (Figure 2 and Test 3a, page 32). Therefore, the present inventors conclude that xanthohumol and 8-prenylnaringenine are not necessary or even have negative impact in the treatment of a bone mineral density reduction or osteoporosis, which is not taught by the prior art.

In light of the foregoing, it is apparent that the cited art does not place in the hands of the interested public a method for inhibiting bone mineral density reduction or for treating osteoporosis by administering an active ingredient that is isoxanthohumol. Necessarily, therefore, Bourges-Sevenier fails as an anticipatory reference. Accordingly, withdrawal of the anticipation rejection is requested.

#### **IV. Rejection of Claims under 35 U.S.C. § 103(a)**

The Examiner rejected claims 27-28 and 31-45 for alleged obviousness over Bourges-Sevenier and PCT Publication No. WO 03/014287 by Erdelmeier et al., the corresponding U.S.

Publication No. 2005/0042318 of which is referred to as "Erdelmeier." Applicants respectfully traverse the rejection.

Bourges-Sevenier is discussed above. Erdelmeier is cited for the alleged teaching of ethanol extraction, heating in alkaline water under reflux, and including the active ingredient in the drinks, such as tea, milk, yoghurt, and the specific amount consumed everyday. Similar to Bourges-Sevenier, Erdelmeier also fails to disclose an active ingredient that is isoxanthohumol for treating a bone mineral density reduction or osteoporosis. Accordingly, the cited references in combination do not render the claimed invention obvious, and withdrawal of the rejection is warranted.

### CONCLUSION

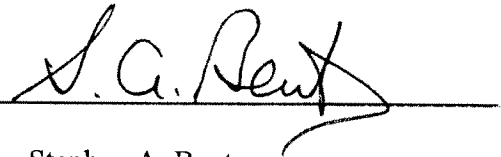
Applicants submit that this application is in condition for allowance, and an early indication to this effect is requested. Examiner Chen is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required regarding this application under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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By



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